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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,301	02/01/2002	Yusuke Nakamura	1254-0195P	7091

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SA-

Office Action Summary	Application No.	Applicant(s)	
	10/060,301	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-5 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 01 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action responds the Amendment received on April 21, 2004.

Oath/Declaration

The objection to the Oath for missing inventor signatures, made in the Office Action mailed on October 22, 2003 is withdrawn as the original oath properly contained all of the signatures. Applicants are greatly appreciated for supplying a copy of the signed oath in their response.

Claim Objections

The objection to claims 1 and 2 for containing informalities, made in the Office Action mailed on October 22, 2003 is withdrawn in view of the Amendment received on April 21, 2004.

Claim Rejections - 35 USC § 112 – Necessitated by Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicants have amended the independent claim 1 to recite the limitation,
“simultaneously amplifying a plurality of nucleotide sequences comprising at least one or more

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sites of single nucleotide polymorphism using genomic DNA whose amount is 10-40 ng per 100 sites and a plurality of primer pairs,” thereby necessitating the instant rejection.

The support for the above limitation, according to Applicants, is found on bottom of page 4 to page 5 of the specification.

The cited section of the specification discloses the below:

“In such amplification step, a preferred amount of a template DNA is 10 to 40 ng when, for example, nucleotide sequences of *100 regions are amplified using 100 pairs of primers*. When the amount of template DNA is less than 10 nm, amplifying all 100 regions would be difficult.”

Therefore, the specification provides written support for the scope of a method of amplifying using 10-40 ng of genomic DNA having 100 target sites using 100 pairs of primers. However, the method as amended encompasses the use of 10-40 ng of genomic DNA using at least a primer pair (as denoted by the phrase, “one or more sites of single nucleotide polymorphism”), thus encompassing a genus of range. Additionally, the claims do not require that a 100 pairs of primers be used, but encompass a method of amplifying at least one polymorphic site in a genomic DNA using 10-40 ng, so long as the genomic DNA contains 100 polymorphic sites. Finally, the claim also appear to encompass a method of amplifying a single polymorphic site in a genomic DNA, wherein the amount of genomic DNA to be used would be in the range of 0.1-0.4 ng (as denoted by the phrase, “10-40 ng *per* 100 sites.” Such broad genus is not properly supported by the above-cited section of the specification, failing to properly provide adequate written description for the breadth of the amended claims.

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Claim Rejections - 35 USC § 102

The rejection of claims 1-5 under 35 U.S.C. 102(a) as being anticipated by Ohnishi et al. (Journal of Human Genetics, August 2001, vol. 46, no. 8, pages 471-477), made in the Office Action mailed on October 22, 2003 is withdrawn in view of the Declaration under 37 CFR 1.132 received on April 21, 2004.

Rejection – Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1 and 5 under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Science, May 1998, vol. 280, pages 1077-1082), made in the Office Action mailed on October 22, 2003 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on April 21, 2004 have been fully considered, but they are not found persuasive for the following reasons.

Applicants argue that at least the independent claim 1 has been amended to require the use of using genomic DNA whose amount is 10-40 ng per 100 sites and since the reference fails to teach this method, the claimed method cannot be anticipated (page 6, Response).

Applicants are reminded that the claims as amended do not require that all 100 sites be amplified nor detected. The claims read on a method of identifying at least one (as denoted by the phrase, "one or more") polymorphic site in 10-40 ng of genomic DNA using a plurality of primers, so long as the genomic DNA comprises 100 sites.

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As already discussed Wang et al. disclose a method of SNP genotyping which involves multiplex amplification from a genomic DNA via use of a plurality of primer pairs (page 1080), wherein the multiplex amplification involves 46 loci from a genomic DNA (page 1080, 3rd column). In fact, Wang et al. disclose a multiplex amplification, wherein the multiplex amplification is achieved ranging from 23 to 558 polymorphic sites (page 1080, 3rd column), thus rendering the invention as claimed anticipated.

The rejection of claims 1, 2, and 4 under 35 U.S.C. 102(b) as being anticipated by Walburger et al. (Mutation Research, January 2001, vol. 432, pages 69-78), made in the Office Action mailed on October 22, 2003 is maintained for the reasons of record.

Applicants arguments presented in the Amendment received on April 21, 2004 have been fully considered but they are not found persuasive for the following reasons.

The reasoning for the anticipation has already been discussed above and since the same arguments have been made for both of the rejections (Wang et al. and Walburger et al.) by Applicants, the instant rejection is maintained for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (Science, May 1998, vol. 280, pages 1077-1082) in view of Brooks (US 2001/0046670 A1, issued November 29, 2001, priority October 7, 1999), made in the Office Action mailed on October 22, 2003 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on April 21, 2004 have been fully considered but they are not found persuasive for the following reasons.

Applicants argue that the claims as amended are not anticipated by the primary reference Wang et al. and therefore, cannot be combined with Brooks reference to render obvious the invention. As already set forth above, Wang et al. anticipate the claims as amended for the claims do not require that all 100 sites be amplified nor detected. As such reasoning has already been discussed above, and since Applicants have not set forth any new arguments, the rejection is maintained for the reasons of record.

The rejection of claim 3 under U.S.C. 103(a) as being unpatentable over Walburger et al. (Mutation Research, January 2001, vol. 432, pages 69-78) in view of Wang et al. (Science, May 1998, vol. 280, pages 1077-1082), made in the Office Action mailed on October 22, 2003 is maintained for the reasons of record.

Applicants argue that the claims as amended are not anticipated by the primary reference Walburger et al. and therefore, cannot be combined with Wang et al. reference to render obvious the invention. As already set forth above, Walburger et al. anticipate the claims as amended for the claims do not require that all 100 sites be amplified nor detected. As such reasoning has

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already been discussed above, and since Applicants have not set forth any new arguments, the rejection is maintained for the reasons of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

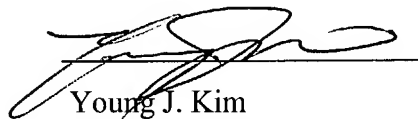
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637


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by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Young J. Kim
Patent Examiner
Art Unit 1637
7/8/04

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7/12/04